

PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0951-0031

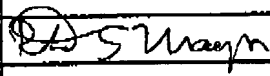
U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

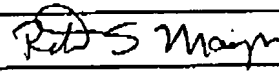
TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/702,194	RECEIVED CENTRAL FAX CENTER JUL 06 2007
	Filing Date	November 4, 2003	
	First Named Inventor	Stephen Solomon et al.	
	Art Unit	3761	
	Examiner Name	Melanie Hand	
Total Number of Pages In This Submission	Attorney Docket Number	11973-003	

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input checked="" type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input type="checkbox"/> Other Enclosure(s) (please identify below):
Remarks		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	PROSKAUER ROSE LLP		
Signature			
Printed name	Robert S. Mayer		
Date	July 6, 2007	Reg. No.	38,544

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:	
Signature	
Typed or printed name	Robert S. Mayer
Date	July 6, 2007

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PROSKAUER ROSE LLP

1585 Broadway
New York, NY 10036-8299
Telephone 212.969.3000
Fax 212.969.2900

LOS ANGELES
WASHINGTON
BOSTON
BOCA RATON
NEWARK
NEW ORLEANS
PARIS

Date July 6, 2007 Client-Matter 11973-003

Total Pages (Including Cover)

From Robert S. Mayer

Sender's Voice Number 212.969.3246

Sender's Email Address rmayer@proskauer.com

To:
Company: United States Patent & Trademark Office

Fax Transmittal

RECEIVED
CENTRAL FAX CENTER

JUL 06 2007

Sender's Room Number 1632

Main Fax Number 212.969.2900

Fax No.: 571-273-8300

Voice No.:

Message

In re the Application of:

Stephen Solomon et al.

Application No.: 10/702,194

Filed: November 4, 2003

**For: FOOD EXTRACTION APPARATUS
AND METHOD**

Group Art Unit: 3761

Examiner: Melanie Hand

REPLY TO EXAMINER'S ANSWER

Confidentiality Note: This message is confidential and intended only for the use of the addressee(s) named above. It may contain legally privileged material. Dissemination, distribution or copying of this message, other than by such addressee(s), is strictly prohibited. If you have received this message in error, please immediately notify us by telephone and return the original to us at the address above. We will reimburse you for the cost of the telephone call and postage. Thank you.

Application No. 10/702,194
Attorney Docket: 11973-003

RECEIVED
CENTRAL FAX CENTER
JUL 06 2007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Stephen Solomon et al.

Application No.: 10/702,194

Filed: November 4, 2003

For: FOOD EXTRACTION APPARATUS
AND METHOD

Group Art Unit: 3761

Examiner: Melanie Hand

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY TO EXAMINER'S ANSWER

Sir:

This paper is a response to the Examiner's Answer mailed May 7, 2007, a response to which is due on Monday, July 9, 2007.

The Commissioner is authorized to charge any fees required in connection with this paper to Deposit Account No. 16-2500.

Application No. 10/702,194
Attorney Docket: 11973-003

Status of Claims

Claims 17, 18 and 32-34 are pending and are the subject of this appeal. Claims 17 and 32-34 are independent. Claims 32-34 stand rejected under 35 U.S.C. § 112, second paragraph. Claims 17, 18 and 32-34 stand rejected under 35 U.S.C. § 103 as being unpatentable over Shapiro. Claims 1-15 and 20 were previously withdrawn as not directed to the elected invention. Claims 16, 19 and 21-31 were previously cancelled without prejudice or disclaimer.

Application No. 10/702,194
Attorney Docket: 11973-003

Grounds of Rejection to Be Reviewed on Appeal

- I. Whether claims 32-34 fail to set forth the subject matter which applicants regard as their invention under 35 U.S.C. § 112, second paragraph.
- II. Whether claims 17 and 18 are unpatentable under 35 U.S.C. § 103 over Shapiro.
- III. Whether claims 32-34 are unpatentable under 35 U.S.C. § 103 over Shapiro.

RECEIVED
CENTRAL FAX CENTER

JUL 06 2007

Application No. 10/702,194
Attorney Docket: 11973-003

RECEIVED
CENTRAL FAX CENTER

JUL 06 2007

Argument

a. Introduction

Obesity is a medical condition with a well-accepted definition: an adult is considered to be obese when their body mass index (BMI) exceeds 30. *See, e.g.*, the definition from the Centers for Disease Control and Prevention Agency of the United States Department of Health and Human Services ("the CDC"), attached as Appendix A; and the overweight and Obesity classification table from the National Institute of Health, attached as Appendix B.¹

The Examiner's Answer fails to appreciate that obesity is a term with an accepted meaning, and apparently considers a person who has experienced any weight gain, no matter how small, as being "obese." This is clear from the last paragraph on page 7 of the Examiner's Answer, which states that "while the [subject] may not be obese upon the first cycle of ingesting foodstuffs, the rat necessarily becomes obese prior to the drawing out of said foodstuffs." It is also clear from the next sentence, which states that "[b]ulimics can also be considered obese," even though bulimia and obesity are two distinct medical conditions, and most bulimics are not obese. See the CDC glossary entry for bulimia, attached as Appendix C, which defines bulimia as "a disorder marked by morbidly increased appetite, often alternating with periods of anorexia." Notably, the definition of bulimia is not dependent on BMI or obesity.

Although ingesting one pound of food at a single meal will temporarily cause a person's weight to increase by one pound, ingesting that single meal does not make the person obese because it does not cause the person's BMI to increase above the threshold of 30. Since being

¹ It was necessary to add Appendices A-C in this Reply to address the Examiner's incorrect interpretation of "obese," which appeared for the first time in the Examiner's Answer.

Application No. 10/702,194
Attorney Docket: 11973-003

“obese” has an accepted medical definition, the claims’ references to “obese” must be read in view of that definition.

b. The Rejections of Claims 32-34 under 35 U.S.C. § 103 and § 112, ¶ 2

Claims 32 and 33 recite the steps of introducing a tube or passageway through an obese patient’s abdominal wall, allowing the obese patient to ingest food, extracting the food from the obese patient, and repeating the steps of ingesting and extracting food until the patient is no longer obese. Claim 34 is similar to claims 32 and 33 except that claim 34 does not recite the step of introducing a tube or passageway through the obese patient’s abdominal wall. Since Shapiro does not describe the steps of introducing a tube or passageway through an obese patient’s abdominal wall, allowing the obese patient to ingest food, or extracting the food from the obese patient, applicants submit that the limitations recited in the claims are not taught or suggested by Shapiro, which was a study designed to mimic bulimia.

The significance of the limitations reciting that the patient must be obese in claims 32 - 34 is supported by *Perricone v. Medicis Pharmaceutical Corp.*, 77 USPQ2d 1321 (Fed. Cir. 2005). In situations when a new use is positively recited in the steps of a method claim, “new uses of old products or processes are indeed patentable subject matter.” *Id.* Following the same reasoning, in order to properly reject claims 32-34, the Examiner has the burden of finding prior art where food was extracted from the upper digestive system of an obese patient, and where it is done via a tube or passageway through the obese patient’s abdominal wall. Since Shapiro fails to teach or suggest “extracting the food from the upper digestive system of [an] obese patient,” this limitation is not satisfied by the cited art.

Application No. 10/702,194
Attorney Docket: 11973-003

In addition, the limitation of “repeating steps...until the patient is no longer obese.” constitutes a time-related limitation that specifies how long the previous steps must be repeated, i.e., until such time that the subject is no longer obese. This is another concept that is neither taught nor suggested by Shapiro, which was an experiment designed to mimic bulimia – not obesity. Since bulimia and obesity are two independent diseases, as explained above, the Examiner’s reliance on Shapiro is not appropriate in the context of obesity.

Finally, Applicants’ reiterate their understanding of Shapiro as an author who is critiquing the use of animal models in eating disorder research. (See page 111). Applicants do not take Shapiro out of context since Shapiro states “[i]n the second part, I provide a critique of the particular models presented.” Shapiro at page 111. Shapiro does mock the use of animal research in understanding eating disorders. This is apparent from his sarcastic remark found at page 144 in which he rhetorically asks, “[w]hat could be more farfetched than studying the peculiar and apparently culturally driven psychology and behavior of bulimia by observing the eating behavior of a rat whose stomach has a hole cut into it...?” Ultimately, the author reaches the conclusion that “animal models have contributed virtually nothing toward the effective treatment of eating disorders.” (See page 210). Accordingly, Applicants submit that it would not have been obvious to modify the method in Shapiro for the purpose of treating obese patients. Shapiro teaches away from the use of animal models in treating eating disorders. A reference that teaches away cannot render claims obvious.

Since claims 32-34 contain limitations that are neither taught nor suggested by Shapiro, Applicants submit that those claims are not obvious over that reference, and respectfully request reversal of the rejection of those claims under 35 U.S.C. § 103. In addition, since neither the

Application No. 10/702,194
Attorney Docket: 11973-003

steps of the methods recited in claims 32-34 nor the results obtained when those methods are performed are the same as in Shapiro (the results differ because bulimics usually do not lose weight despite their binge-purge behavior), Applicants respectfully request reversal of the rejections under 35 U.S.C. § 112, second paragraph.

c. The Rejections of Claims 17 and 18 under 35 U.S.C. § 103

The last two steps of claim 17 are: [a] monitoring a volume of the pumped food; and [b] ending the pumping when the monitored volume exceeds preset parameters within a given time. Even if one were to accept the Examiner's argument that the "monitoring" step is inevitably performed by the pump operator, the Examiner has not pointed to anything in Shapiro that teaches or suggests "ending the pumping when the monitored volume exceeds preset parameters within a given time," and has proposed no motivation why a person of ordinary skill might be led to end the pumping at such time.

To the contrary – since the last paragraph of page 125 of Shapiro describes sham feeding as a process in which "the animal eats or drinks without receiving nutritional benefits," a person following the teachings of Shapiro would not be motivated to end the pumping after a certain volume has been pumped out within a given time. Instead, a person following the teachings of Shapiro would be motivated to continue pumping until as much food as possible has been removed. Applicants therefore submit that the Examiner has not made a prima facie case of obviousness because "to establish a prima facie obviousness of a claimed invention, all the claim limitation must be taught or suggested by the prior art." See M.P.E.P. § 2143.03. Applicants therefore respectfully ask the Board to reverse this rejection as well.

Application No. 10/702,194
Attorney Docket: 11973-003

Applicants' undersigned attorney may be reached by telephone at (212) 969-3686 or by facsimile at (212) 969-2900. Please continue to direct all correspondence to Customer No. 21890 at the address provided below.

Respectfully submitted,

PROSKAUER ROSE LLP

Date: July 6, 2007

By:



Robert S. Mayer
Attorney for Applicants
Registration No. 38,544

Proskauer Rose LLP
Patent Department
1585 Broadway
New York, NY 10036-8299
Tel. (212) 969-3686 (direct)
Fax (212) 969-2900

APPENDIX A



Defining Overweight and Obesity

Overweight and obesity are both labels for ranges of weight that are greater than what is generally considered healthy for a given height. The terms also identify ranges of weight that have been shown to increase the likelihood of certain diseases and other health problems.

Definitions for Adults

For adults, overweight and obesity ranges are determined by using weight and height to calculate a number called the "body mass index" (BMI). BMI is used because, for most people, it correlates with their amount of body fat.

- An adult who has a BMI between 25 and 29.9 is considered overweight.
- An adult who has a BMI of 30 or higher is considered obese.

See the following table for an example.

Height	Weight Range	BMI	Considered
5' 9"	124 lbs or less	Below 18.5	Underweight
	125 lbs to 168 lbs	18.5 to 24.9	Healthy weight
	169 lbs to 202 lbs	25.0 to 29.9	Overweight
	203 lbs or more	30 or higher	Obese

It is important to remember that although BMI correlates with the amount of body fat, BMI does not directly measure body fat. As a result, some people, such as athletes, may have a BMI that identifies them as overweight even though they do not have excess body fat. For more information about BMI, visit [Body Mass Index](#).

Other methods of estimating body fat and body fat distribution include measurements of skinfold thickness and waist circumference, calculation of waist-to-hip circumference ratios, and techniques such as ultrasound, computed tomography, and magnetic resonance imaging (MRI).

Definitions for Children and Teens

For children and teens, BMI ranges above a normal weight have different labels (at risk of overweight and overweight). Additionally, BMI ranges for children and teens are defined so that they take into account normal differences in body fat between boys and girls and differences in body fat at various ages. For more information about BMI for children and teens (also called BMI-for-age), visit [BMI for Children and Teens](#).

<http://www.cdc.gov/print.do?url=http%3A%2F%2Fwww.cdc.gov%2Fncddphp%2Fdnpa%2Fobesity...> 7/6/2007

Assessing Health Risks Associated with Overweight and Obesity


BMI is just one indicator of potential health risks associated with being overweight or obese. For assessing someone's likelihood of developing overweight- or obesity-related diseases, the National Heart, Lung, and Blood Institute guidelines recommend looking at two other predictors:

- The individual's waist circumference (because abdominal fat is a predictor of risk for obesity-related diseases).
- Other risk factors the individual has for diseases and conditions associated with obesity (for example, high blood pressure or physical inactivity).

For more information about the assessment of health risk for developing overweight- and obesity-related diseases, visit the following Web pages from the National Heart, Lung, and Blood Institute:

- [Assessing Your Risk](#)
- [Body Mass Index Table](#)
- [Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults](#)

[back to top](#)

 Please note: Some of these publications are available for download only as *.pdf files. These files require Adobe Acrobat Reader in order to be viewed. Please review the [information on downloading and using Acrobat Reader software](#).

* Links to non-Federal organizations found at this site are provided solely as a service to our users. These links do not constitute an endorsement of these organizations or their programs by CDC or the Federal Government, and none should be inferred. CDC is not responsible for the content of the individual organization Web pages found at these links.

Page last reviewed: May 22, 2007

Page last updated: May 22, 2007

Content Source: [Division of Nutrition and Physical Activity, National Center for Chronic Disease Prevention and Health Promotion](#)

Page Located on the Web at <http://www.cdc.gov/nccdphp/dnpa/obesity/defining.htm>

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
SAFER • HEALTHIER • PEOPLE™

APPENDIX B

NHLBI, Classification and Risks of Overweight and Obesity

Page 1 of 1

DEPARTMENT OF HEALTH AND HUMAN SERVICES • NATIONAL INSTITUTES OF HEALTH



National Heart Lung and Blood Institute • Obesity Education Initiative

[Healthy Weight Home](#) • [BMI Calculator](#) • [Menu Planner](#) • [Portion Distortion](#) • [WeCan!](#)

Classification of Overweight and Obesity by BMI, Waist Circumference, and Associated Disease Risks

	BMI (kg/m ²)	Obesity Class	Disease Risk* Relative to Normal Weight and Waist Circumference	
			Men 102 cm (40 in) or less Women 88 cm (35 in) or less	Men > 102 cm (40 in) Women > 88 cm (35 in)
Underweight	< 18.5		-	-
Normal	18.5 - 24.9		-	-
Overweight	25.0 - 29.9		Increased	High
Obesity	30.0 - 34.9	I	High	Very High
	35.0 - 39.9	II	Very High	Very High
Extreme Obesity	40.0 +	III	Extremely High	Extremely High

* Disease risk for type 2 diabetes, hypertension, and CVD.

+ Increased waist circumference can also be a marker for increased risk even in persons of normal weight.

[Back](#)


Key Recommendations • Assessing Risk • Controlling Weight • BMI Tables
Shaping What to Eat • Fat • Sugars • Sodium • Portion Sizes • Food Exchanges • All
Selecting a Program • Guide to Physical Activity • Guide to Behavior Change • Do Share
Daily Food and Activity Diaries • Publications

Professional Education Materials • Patient & Public Education Materials
Healthy Weight Home • BMI Calculator • Menu Planner • Portion Distortion • WeCan!

NHLBI Home • Q&A Home • NHLBI Privacy Statement • Contact the NHLBI • Accessibility



APPENDIX C

RECEIVED
CENTRAL FAX CENTER

JUL 06 2007

Page 1 of 1

CDC - CFS Glossary

B**bile duct**

Tubular structures responsible for conducting bile (a substance that aids in digestion) from the liver to the intestine.

biliary obstruction

Blockage or clogging of a bile duct.

bilirubin

A red pigment formed from hemoglobin during normal and abnormal destruction of red blood cells in the body.

bipolar affective disorder

A mood disorder that commonly begins with depression and is characterized by at least one period of elation sometime during the course of the illness.

Borrelia

A genus of bacteria with numerous species that cause disease in humans. The diseases associated with these organisms are typically relapsing fevers.

bulimia nervosa

A disorder marked by morbidly increased appetite, often alternating with periods of anorexia.